REMARKS

Claims 4, 6, 8, 10, and 16-18 are all the claims pending in the application.

Claims 4, 17, and 18 have been amended to recite that the composition is in an amount of at least 10^6 cells/g. Support for these amendments to claims 4, 17, and 18 can be found at page 21, line 20 of the present specification. Claim 4 has been further amended to recite that the composition is in the form of a food or beverage for a mammal. Claims 4, 17, and 18 have further been amended to clarify *Lactobacillus* nomenclature.

No new matter is added. Entry of the Amendment is respectfully requested.

I. Response to Objection to the Specification

On page 2 of the Action, the specification is objected to under 35 U.S.C. § 112 for not referring to *Lactobacillus* ONRIC b0240 (FERM BP- 100605) as *Lactobacillus pentosus* ONRIC b0240 (FERM BP- 100605).

In response, Applicants provide a substitute specification having updated *Lactobacillus pentosus* ONRIC b0240 (FERM BP- 100605) nomenclature.

Accordingly, withdrawal of the objection to the specification is requested.

II. Response to Claim Rejections Under 35 U.S.C. § 112

A. On page 2 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to reasonably convey possession of the claimed invention.

The Examiner asserts that the claims should recite *Lactobacillus pentosus* ONRIC b0240 (FERM BP- 100605) instead of *Lactobacillus* ONRIC b0240 (FERM BP- 100605). In addition, the Examiner contends that the phrase "in an amount effective to promote human IgA production in mucosae" in claim 18 raises new matter issues because the portion of the specification relied

upon to support the amendment only applies to "intestinal mucosae, not to all mucosae, including the respiratory mucosae, for example."

Solely to advance prosecution, Applicants amend claims 4, 17 and 18 herein to recite *Lactobacillus* nomenclature and delete any alleged contested terminology, thereby rendering the rejection moot.

Withdrawal of the rejection of claims 4, 6 and 16-18 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

B. On page 3 of the Action, claims 4, 6, and 16-18 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

With regard to claims 4, 6, and 16-17, the Examiner states that Applicants do not recite an "amount effective" to stimulate mucosal immunity which can be applied to any and all subjects, including mammals, fish, humans, etc.

With regard to claim 18, the Examiner states that an effective amount "to promote human IgA production in mucosae" is vague and indefinite because it cannot be readily ascertained by the specification.

In response, Applicants have amended claims 4, 16, and 17 to recite that the composition is in an amount of at least 10^6 cells/g. Furthermore, Applicants have amended claim 4 to recite that the composition is in the form of a food or beverage for a mammal.

In view of the above, Applicants submit that the amendments to claims 4, 16, and 17 have overcome the rejection.

Withdrawal of the rejection of claims 4, 6, and 16-18 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

C. On pages 3-4 of the Action, claims 4, 6, and 16-18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirement.

The Examiner asserts that the claims are broadly directed to stimulate mucosal immunity and to promote human IgA production but do not provide guidance on a specific amount of cells required for the touted properties. In contrast, the Examiner contends that Applicants only provide broad guidance on the amount of these strains required in a murine model, which is not "reasonably predictive of the activity of strains in any and all environments" and "subjects."

In response and without acquiescing to the merits of the rejection, Applicants have amended claims 4, 17, and 18 to recite that the composition is in an amount of at least 10^6 cells/g. Applicants submit that the amendment to claims 4, 16, and 17 have overcome the rejection.

Withdrawal of the rejection of claims 4, 6, and 16-18 under 35 U.S.C. § 112, first paragraph is requested.

III. Response to Claim Rejection Under 35 U.S.C. § 102/103

At page 5-6 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ikenaga et al. (Milk Science, 2002, 51: 27-32, hereinafter Ikenaga) or Perdigon et al. (J. Dairy Sci., 1999, 82:1108-1114, hereinafter Perdigon) or Herias et al. (Clin. Exp. Immunol., 1999, 116:283-290, hereinafter Herias), for reasons of record.

In the Office Action, the Examiner asserts that the cited references each disclose a *Lactobacillus plantarum* strain that appears to be the same as the present strains, and thus the reference strains would expect to stimulate mucosal immunity and inherently possess the same characteristics as the claimed strains.

Applicants respectfully traverse.

The presently claimed *Lactobacillus plantarum* ONRIC b0239 (FERM BP-10064) and *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065) exhibited IgA production enhancement abilities superior to any of the strains disclosed in Ikenaga, Perdigon, or Herias. Thus, Ikenaga, Perdigon, or Herias recite strains that do not inherently possess the same characteristics as the claimed strains and thus cannot be said to anticipate the present claims.

In addition and without acquiescing to the merits of the rejection, Applicants amend claims 4, 17, and 18 herein to recite that the composition is in an amount of at least 10^6 cells/g. In view of this amendment to the claims and in view of the attached Declaration, Applicants submit that satisfactory mucosal immunostimulation activity can be attained when the strains of the present invention are used, even at a concentration of 10^6 cells/ml or less.

In support of this amendment to claims 4, 16, and 17, Applicants submit a Declaration under 37 C.F.R. § 1.132. The attached Declaration shows that the IgA production is increased by the intake of a composition or a pharmaceutical composition comprising a strain of lactic acid bacteria selected from the group consisting of *Lactobacillus* plantarum ONRIC b0239 (FERM BP-10064) and *Lactobacillus* pentosus ONRIC b0240 (FERM BP-10065).

Importantly, the Declaration also shows that the bacteria do not need to be administered at a concentration of 10^9 cells/g or at any particular threshold concentration. This is because the effect of stimulating mucosal immunity and the effect of promoting human IgA production in mucosa of this invention neither weakens nor disappears, even if the concentration of *Lactobacillus* is increased. None of the strains of Ikenaga, Perdigon, or Herias inherently possesses the mucosal immunity and the human IgA production promoting effects of the present

strains. Accordingly, Applicants submit that none of Ikenaga, Perdigon, or Herias anticipates the present claims.

In response to the Examiner's contention that the claimed strains, if not anticipated by the cited references are rendered obvious, Applicants respectfully disagree for the following reasons.

It has conventionally been known that various types of lactic acid bacteria have IgA production enhancement abilities. However, the recited strains of the present invention, i.e., *Lactobacillus plantarum* ONRIC b0239 (FERM BP-10064) and *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065) have remarkably excellent IgA production enhancement abilities that could not have been expected from conventionally known lactic acid bacteria.

Example 2 (Tables 1 to 4) of the present specification clearly shows the excellent IgA production enhancing activity of the lactic acid bacteria of the invention. Further, the Declarations dated February 20, 2009 and October 29, 2009 also are probative of the clearly superior effects of the present invention.

For example, in Example 2 of the present specification, the IgA Stimulation Index (S.I.) was measured for 150 bacterial stains. The results show that the only strains having an IgA S.I. greater than 5 were the presently claimed *Lactobacillus plantarum* ONRIC b0239 (FERM BP-10064) and *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065). Comparatively, every one of the other 148 strains of known lactic acid bacteria exhibited IgA production enhancing activity less than half than the IgA production enhancing activity of either of the claimed strains.

Similarly, the Declaration dated February 20, 2009 clearly demonstrates that every one of the tested 59 strains of lactic acid bacteria exhibited an IgA production enhancement ability that is less than half than the IgA production enhancing activity of either of the claimed strains. As is clear from the Declaration, presently claimed *Lactobacillus plantarum* ONRIC b0239 (FERM

BP-10064) and *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065) are superior to the *Lactobacillus plantarum* 299v stain disclosed in Herias.

As is also clear from the Declaration dated October 29, 2009, presently claimed *Lactobacillus plantarum* ONRIC b0239 (FERM BP-10064) and *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065) exhibited IgA production enhancement abilities superior to the ONC141 strain disclosed in Ikenaga.

In view of the results of Example 2 of the present specification and the above-mentioned Declarations, a skilled artisan conducting a screening to detect a strain that exhibits an unexpectedly superior ability to produce IgA would require an excessive amount of trial and error to identify a strain possessing the IgA production and mucosal immunity abilities of the claimed strains. Accordingly, Applicants submit that it is clear that a person having ordinary skill in the art would not have easily attained the present invention.

Regarding the strains disclosed in Perdigon, Perdigon discloses the following: "Control," "*Lactobacillus rhamnosus* CRL74," "*Lactococcus lactis* CRL526," "*Lactobacillus acidophilus* CRL924," "*Lactobacillus casei* CRL431," "*Lactobacillus delbrueckii ssp. Bulgaricus* CRL423," "*Streptococcus salvarius spp. Thermophilus* CRL412" and "*Lactobacillus plantarum* CRL936" (see page 1109, right column, "Microorganisms Used" and Figure 2).

Among these strains, only "*Lactobacillus plantarum* CRL936," "*Lactobacillus delbrueckii ssp. Bulgaricus* CRL423," and "*Lactobacillus acidophilus* CRL924" have relatively high $IgA^{+}B$ cell concentrations.

Although present Tables 1 to 4 of the present specification do not specifically include a comparison of the above Perdigon strains, similar strains are compared in the Tables. Accordingly, a predictable model for determining the IgA S.I. value of the Perdigon strains can

be established. For example, in view of Tables 1 to 4 of the present specification, it can be safely assumed that *Lactobacillus plantarum* CRL936 has an IgA S.I. of 0.96-1.66, *Lactobacillus delbrueckii ssp. Bulgaricus* CRL423 has an IgA S.I. of 1.07 and 1.23, and *Lactobacillus acidophilus* CRL924 had an IgA S.I. of 1.10. Each of these values is less than half that of the presently claimed strains.

Further, the Declaration dated February 20, 2009 also indicates that the IgA S.I. of conventionally-known *plantarum* is 0.06 to 2.46, which is similarly less than half that of the two strains of the present invention.

Accordingly, Applicants submit that "*Lactobacillus plantarum* CRL936" disclosed in Perdigon has as low an IgA production enhancement ability similar to those strains disclosed in Tables 1 to 4 in the instant specification and as low as those of the strains shown in the Declaration dated October 29, 2009 (excluding the presently claimed strains).

Thus, in view of the above evidence, Applicants submit that the presently claimed strains have a IgA production enhancement ability that is unexpectedly superior to the "*Lactobacillus plantarum* CRL936" of Perdigon.

Accordingly, the instantly claimed strains possess unexpectedly superior IgA-stimulating activity vis-à-vis the strains of the cited references, and such is probative of the non-obviousness of the claimed invention. It is well-settled that a demonstration of unexpected results, or unexpected superiority of a particular result or property, may rebut a finding of obviousness. Applicants respectfully submit that in view of such unexpectedly superior properties of the instantly claimed invention, the cited references, taken alone or in combination, do not render obvious Applicants' claimed invention.

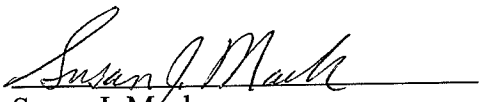
Reconsideration and withdrawal of the rejection under § 102(b) and § 103(a) is respectfully requested.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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